

ATTACHMENT 1

In re National Prescription Opiate Litigation: MDL 2804

Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Memorandum in Opposition to Defendants' Motion to Exclude Seth Whitelaw's Opinions and Proposed Testimony

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Issue 1: Should the opinions of Dr. Seth B. Whitelaw be excluded?

Answer: No. Defendants contend that Dr. Whitelaw's opinions should be excluded because he is unqualified to testify about DEA suspicious order monitoring programs, his methodology is unreliable, and he offers opinions on an ultimate issue in the litigation. Each of these arguments lack merit. **First**, Dr. Whitelaw is fully qualified to offer his opinions. He has 30 years of experience in the life science compliance industry in which he offers testimony, and, contrary to Defendants' assertions, his expertise includes anti-diversion compliance. *See Rheinfrank v. Abbott Labs, Inc.*, 2015 WL 13022172, at *14 (S.D. Ohio Oct. 2, 2015), *aff'd*, 680 F. App'x 369 (6th Cir. 2017) (expert qualified to opine regarding defendants' compliance with FDA regulations; questions regarding expert's experience go to credibility and may be addressed on cross-examination). **Second**, Dr. Whitelaw's methodologies are reliable, well-accepted, and widely used by compliance professionals. In fact, Defendants themselves both explicitly and implicitly incorporate Dr. Whitelaw's methodologies as part of their compliance programs, including their anti-diversion efforts. Dr. Whitelaw's use of these methodologies is consistent with his practice outside of litigation. *See In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, 2010 WL 1796334, at *6 (N.D. Ohio May 4, 2010) (expert theory reliable where experts' research related "not only to their review of the literature but to matters growing naturally or necessarily out of research they have conducted independent of this litigation"), *aff'd sub nom.*, *Decker v. GE Healthcare Inc.*, 770 F.3d 378 (6th Cir. 2014). **Finally**, Dr. Whitelaw does not opine on whether Defendants have acted contrary to any specific laws or regulations. Instead, Dr. Whitelaw offers opinions concerning the proper elements of a compliance program for a reasonable manufacturer and distributor and offers an assessment of Defendants' compliance programs based upon those elements. His testimony will assist the jury in understanding the complex regulatory scheme applicable to opioid manufacturers and distributors. *See Allied Erecting & Dismantling Co., Inc. v. Genesis Equip. & Mfg., Inc.*, 2009 WL 8592874, at *4 (N.D. Ohio Aug. 12, 2009) (trade secret expert's opinions on subsidiary components of the overall issue "do not invade the province of the jury; rather, his opinions will aid the jury's determination as to whether Allied's information constitutes a trade secret"). Defendants' motion should be denied in full.

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Response Date: July 31, 2019

Reply Date: August 16, 2019